K081138
p1/2

510(k) SUMMARY

Rafael Medical Technologies, Inc.'s SafeFlo® Vena Cava Filter

MAY - 7 2009

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Rafael Medical Technologies, Inc.
3500 South Du Pont Highway
Dover, Delaware 19901

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Contact Person: Aaron Feldman

Date Prepared: April 17, 2008

Name of Device

SafeFlo® Vena Cava Filter

Common or Usual Name

Vena Cava Filter

Classification Name

Cardiovascular Intravascular Filter

Predicate Devices

- Simon Nitinol Filter (C.R. Bard, Inc.)
- OptEase Permanent Vena Cava Filter (Cordis Corp.)

Intended Use / Indications for Use

The SafeFlo® Vena Cava Filter set is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in thromboembolic diseases,
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Technological Characteristics

The SafeFlo Filter is a Nitinol filter designed for simple, stable and safe implantation in the inferior vena cava to allow blood flow towards the heart while preventing the passage of emboli into the pulmonary arteries. The SafeFlo Filter set comprises the vena cava filter unit and a delivery system kit, provided in separate packages.

The SafeFlo Filter is inserted through a 6F (ID) delivery system. The filter is divided into two functional parts, the Double Ring Platform and the Filter Element. The Double Ring Platform is a fixator, which anchors itself in the vessel wall by over-sizing of the rings with respect to the circular diameter of the vessel. The Double Ring Platform has been designed to exit the delivery sheath and rotate through 90° to be positioned perpendicular to the vessel wall. This method of fixation does not utilize individual hooks and therefore vessel trauma is minimized and repositioning is possible.

The Filter Element is the functional unit of the filter; it is shaped from the continuation of the wires of the Double Ring Platform and is thereby supported securely within the bloodstream. The Filter Element's unique double strand structure forms an Outer Support Ring and an inner 5-leafed filtration configuration whose design allows relatively unhindered blood flow and traps clinically significant migrating emboli. The Filter Element's size (diameter) is designed to be up to 3mm smaller than the diameter of the IVC.

Performance Data

Data from bench, animal and clinical testing demonstrates that the SafeFlo Filter functioned as intended and results were as expected.

Substantial Equivalence

The SafeFlo Filter is as safe and effective as the Predicate Devices. The SafeFlo Filter has the same intended uses and indications as well as similar technological characteristics, and principles of operation as its Predicate Devices. The minor technological differences between the SafeFlo Filter and its Predicate Devices raise no new issues of safety or effectiveness. Performance data demonstrate that the SafeFlo Filter is as safe and effective as the Predicate Devices. Thus, the SafeFlo Filter is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Rafael Medical Technologies, Inc.
c/o Ms. Janice Hogan
Hogan and Hartson LLP
1835 Market Street
28th Floor
Philadelphia, PA 19103

Re: K081138
Trade/Device Name: SafeFlo Vena Cava Filter
Regulation Number: 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II
Product Code: DTK
Dated: May 1, 2009
Received: May 1, 2009

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling:

> The safety and effectiveness of the SafeFlo Vena Cava Filter for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the SafeFlo Vena Cava Filter must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081138

Device Name: SafeFlo® Vena Cava Filter

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081138